

U.S. Serial No. 10/586,688

Docket No.: K2100.0001

Amendment In Response to October 23, 2008 Non-Final Office Action
and Petition for One-Month Extension of Time

REMARKS/ARGUMENTS

Claims 1-27 are pending in the subject application. Claims 22-27 have been withdrawn from consideration, and are cancelled hereinabove without prejudice. Claims 1-21 are rejected. Applicants have hereinabove cancelled claim 11, and amended claims 1, 12 and 17. Accordingly, upon entry of this Amendment, claims 1-10 and 12-21, as amended, will be pending and under examination.

Applicants maintain that the amendments to claims 1, 12 and 17 do not raise any new matter, and that the claims, as amended, are fully supported by the specification as originally filed.

In making these amendments, applicants neither concede the correctness of the Examiner's objections and rejections in the October 23, 2008 Non-Final Office Action, nor abandon the right to pursue in a continuing application embodiments of the invention no longer claimed in the subject application.

In view of the arguments set forth below in this Amendment, and claim amendments hereinabove, applicants maintain that the Examiner's objections and rejections made in the October 23, 2008 Non-Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

Claim Objections Under 37 C.F.R. § 1.75(c) (Improper Form)

The Examiner states that claims 11-21 are objected to under 37 C.F.R. § 1.75(c) as allegedly being of improperly dependent form.

In response to the Examiner's objection to claim 11, but without conceding the correctness thereof, applicants note that claim 11 has been cancelled. Therefore, the Examiner's objection to claim 11 is moot.

In response to the Examiner's objection to claims 12-21, but without conceding the correctness thereof, applicants note that claim 12 has been amended to now recite "carrier according to claim 1." Accordingly, the Examiner's objection to claims 12-21, as amended, is obviated.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph (Indefiniteness)

The Examiner states that claims 15 and 16 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner alleges that claim 15 is indefinite since "uptake of an inflammation-mediated cell or enzyme degradations" is a process, and not a drug or substance that would be considered a drug.

In response to the Examiner's rejection, applicants respectfully traverse.

It appears that the Examiner has misread claim 15. Applicants respectfully point out that the claim 15 recites "...the drug is at least one selected from a group consisting of substances that are *activated by*...uptake of an inflammation-mediating cell or enzyme degradation" (emphasis added). Thus, "substances that are activated by...uptake of an inflammation-mediated cell or enzyme degradations" is, at the very least, a substance that would be considered a drug.

In view of the above remarks, applicants maintain that claims 15 and 16 satisfy the requirements of 35 U.S.C. § 112, second paragraph, and request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph (Enablement)

The Examiner states that claims 1-21 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Examiner alleges the specification, while being enabling for (1) a carrier comprising a non-cationic surface that accumulates on an endothelial cell site of damaged tissue, (2) a pharmaceutical composition comprising a carrier comprising a non-cationic surface that accumulates on an endothelial cell site of damaged tissue, wherein the carrier also comprising a drug, and (3) a drug delivery method comprising administering the pharmaceutical composition to an endothelial cell site of tissue damage in a subject, wherein the composition accumulates at said site and wherein the drug of said composition acts on the site of tissue damage, does not reasonably provide enablement for (a) a carrier that accumulates on a damaged tissue site that does not expose or comprise endothelial cells; and (b) a method that does not administer the carrier to a site of tissue damage.

In response to the Examiner's rejection to claim 11, but without conceding the correctness thereof, applicants note that claim 11 has been cancelled. Therefore, the Examiner's rejection to claim 11 is moot.

In response to the Examiner's rejection to claims 1-10 and 12-21, but without conceding the correctness thereof, applicants note that claims 1 and 17 have been amended. Claim 1, as amended, now recites "[a] carrier with a non-cationic surface, which can accumulate on a damaged endothelial cell site of a tissue comprising endothelial cells, wherein the carrier comprises a carboxylic type lipid that has no phosphate group." Claim 17, as amended, now recites "[a] drug delivery method comprising *in vivo* administering the pharmaceutical composition of claim 12 and allowing said composition to accumulate on a damaged site of a tissue."

In view of the above remarks, applicants maintain that claims 1-10 and 12-21, as amended, satisfy the requirements of 35 U.S.C. § 112, first paragraph, and request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections Under 35 U.S.C. § 102(b) (Novelty)

The Examiner states that claims 1-12 and 15 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated over U.S. Patent No. 5,641,662 to Debs et al. ("Debs et al."). Additionally, the Examiner states that claims 1-15 and 17-21 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated over JP 07-089874 to Kazuo et al. ("Kazuo et al."), as evidenced by Dictionary.com (<http://dictionary.reference.com/browse/tinge>).

In response to the Examiner's rejection to claim 11, but without conceding the correctness thereof, applicants note that claim 11 has been cancelled. Therefore, the Examiner's rejection to claim 11 is moot.

In response to the Examiner's rejection to claims 1-10, 12-15 and 17-21, but without conceding the correctness thereof, applicants note that claims 1, 12 and 17 have been amended.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. In the instant case, neither Debs et al. nor Kazuo et al. (as evidenced by Dictionary.com) expressly or inherently describe each and every element as set forth in claims 1, 12 and 17, as amended.

Briefly, amended claim 1 now recites “[a] carrier with a non-cationic surface, which can accumulate on a damaged endothelial cell site of a tissue comprising endothelial cells, wherein *the carrier comprises a carboxylic type lipid that has no phosphate group*” (emphasis added). Amended claim 12 now recites “[a] pharmaceutical composition comprising *the carrier according to claim 1* incorporating or carrying a drug” (emphasis added), and amended claim 17 now recites “[a] drug delivery method comprising *in vivo* administering *the pharmaceutical composition of claim 12* and allowing said composition to accumulate on a damaged site of a tissue” (emphasis added).

Neither Debs et al. nor Kazuo et al. (as evidenced by Dictionary.com) expressly or inherently describe, for example, a “carrier compris[ing] a carboxylic type lipid that has no phosphate group”, which is an element recited in amended claims 1, 12 and 17.

In view of the above remarks, applicants maintain that claims 1-10, 12-15 and 17-21, as amended, satisfy the requirements of 35 U.S.C. § 102(b), and request that the Examiner reconsider and withdraw this ground of rejection.

Conclusion

Applicants maintain that claims 1-10 and 12-21, as amended, are in condition for allowance. Accordingly, allowance is respectfully requested.

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If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

Dated: February 23, 2009

Respectfully submitted,

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